

116TH CONGRESS  
1ST SESSION

# S. 3053

To provide for the regulation, inspection, and labeling of food produced using animal cell culture technology, and for other purposes.

---

IN THE SENATE OF THE UNITED STATES

DECEMBER 16, 2019

Mr. ENZI (for himself and Mr. TESTER) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

---

## A BILL

To provide for the regulation, inspection, and labeling of food produced using animal cell culture technology, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-  
2 tives of the United States of America in Congress assembled,*

**3 SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Food Safety Mod-  
5 ernization for Innovative Technologies Act”.

1   **SEC. 2. REGULATION OF FOOD PRODUCED USING ANIMAL**  
2                   **CELL CULTURE TECHNOLOGY.**

3       Chapter IV of the Federal Food, Drug, and Cosmetic  
4   Act (21 U.S.C. 341 et seq.) is amended by adding at the  
5   end the following:

6   **“SEC. 424. FOOD PRODUCED USING ANIMAL CELL CULTURE**  
7                   **TECHNOLOGY.**

8       “(a) IN GENERAL.—The Secretary shall regulate  
9   food intended for humans that is produced using animal  
10   cell culture technology derived from cell lines of animals  
11   other than livestock or poultry and, in coordination with  
12   the Secretary of Agriculture, food intended for humans  
13   that is produced using animal cell culture technology de-  
14   rived from cell lines of livestock or poultry.

15      “(b) DUTIES.—Pursuant to subsection (a), the Sec-  
16   retary shall—

17       “(1) conduct premarket consultation processes  
18   to evaluate production materials, processes, and  
19   manufacturing controls with respect to food intended  
20   for humans that is produced using animal cell cul-  
21   ture technology, derived from cell lines of livestock  
22   or poultry and food intended for humans that is pro-  
23   duced using animal cell culture technology, derived  
24   from cell lines of animals other than livestock or  
25   poultry, including oversight of tissue collection, cell  
26   lines, cell banks, and all components and inputs;

1           “(2) oversee initial cell collection and the development and maintenance of qualified cell banks, including by issuing regulations or guidance and conducting inspections, as appropriate;

5           “(3) oversee proliferation and differentiation of cells through the time of cell harvest, including by issuing regulations or guidance and conducting inspections, as appropriate;

9           “(4) ensure that cell bank and cell culturing facilities comply with facility registration, applicable good manufacturing practices and preventive controls, and requirements applicable to substances that become a component of food or otherwise affect the characteristics of food;

15          “(5) develop pursuant to notice and comment rulemaking additional requirements for cell bank and cell culturing facility conditions and processes to ensure that biological material exiting the culture process is safe and not adulterated within the meaning of this chapter;

21          “(6) conduct appropriate inspections and follow-up activities, including taking enforcement action if necessary, to ensure that cell bank and cell-culturing facilities are in compliance with applicable laws and regulations;

1                 “(7) coordinate the transfer of regulatory over-  
2         sight of harvested cells derived from livestock or  
3         poultry to the Secretary of the Department of Agri-  
4         culture during cell harvest, including providing such  
5         Secretary with any information necessary to deter-  
6         mine whether harvested cells are eligible to be proc-  
7         essed into food intended for humans that is pro-  
8         duced using animal cell culture technology, derived  
9         from cell lines of livestock or poultry;

10                “(8) inspect establishments that process, pack-  
11         age, and label food intended for humans that is pro-  
12         duced using animal cell culture technology, derived  
13         from cell lines other than livestock or poultry;

14                “(9) promulgate regulations regarding the safe-  
15         ty and accurate labeling of food intended for humans  
16         that is produced using animal cell culture tech-  
17         nology, derived from cell lines other than livestock or  
18         poultry; and

19                “(10) establish appropriate nomenclature for  
20         food intended for humans that is produced using  
21         animal cell culture technology, derived from cell lines  
22         other than livestock or poultry.

23                “(c) COLLABORATION WITH USDA.—In carrying out  
24         this section, the Secretary shall share information, as ap-  
25         propriate, with the Department of Agriculture, including

1 notifying the Department of Agriculture if objectionable  
2 conditions are identified at a facility carrying out any of  
3 the activities described in subsection (b), including condi-  
4 tions which may result in production of adulterated or  
5 misbranded food, collaborating with such department to  
6 address such conditions with respect to the harvesting of  
7 cell cultures, and rely on the Department of Agriculture  
8 to address such conditions with respect to processing,  
9 packaging, and labeling.

10       “(d) LIMITATION.—The Secretary shall not inspect  
11 activities of an establishment that are solely regulated by  
12 the Secretary of Agriculture.

13       “(e) DEFINITIONS.—In this section—

14           “(1) the term ‘livestock’ means cattle, sheep,  
15 swine, goats, and fish of the order Siluriformes; and

16           “(2) the term ‘poultry’ means any domesticated  
17 bird, whether live or dead.

18       “(f) AUTHORITIES RELATED TO LIVESTOCK AND  
19 POULTRY.—Notwithstanding any other provision of law,  
20 the provisions of this section shall not derogate from any  
21 authority under the Federal Meat Inspection Act or Poul-  
22 try Product Inspection Act, as in effect on the date of  
23 enactment of the Food Safety Modernization for Innova-  
24 tive Technologies Act, with respect to the regulation of  
25 meat and poultry produced in the traditional manner.

1       “(g) NO INSPECTION OF FARMS.—Nothing in this  
2 section shall be construed to authorize the Secretary to  
3 conduct an inspection of a farm.”.

4 SEC. 3. INSPECTION AND LABELING OF FOOD PRODUCED  
5 USING ANIMAL CELL CULTURE TECHNOLOGY  
6 FROM LIVESTOCK AND POULTRY CELL  
7 LINES.

8 (a) DEFINITIONS.—In this section:

9                             (1) ADULTERATED.—The term “adulterated”,  
10                             with respect to food intended for humans that is  
11                             produced using animal cell culture technology, de-  
12                             rived from cell lines of livestock or poultry, means  
13                             food—

(B)(i) that bears or contains any added  
poisonous or added deleterious substance (other  
than a substance that is a pesticide chemical  
residue in or on a raw agricultural commodity  
or processed food, a food additive, or a color

1 additive) that is unsafe within the meaning of  
2 section 406 of the Federal Food, Drug, and  
3 Cosmetic Act (21 U.S.C. 346);

4 (ii) that bears or contains a pesticide  
5 chemical residue that is unsafe within the  
6 meaning of section 408(a) of that Act (21  
7 U.S.C. 346a(a)); or

8 (iii) that bears or contains—

9 (I) any food additive that is unsafe  
10 within the meaning of section 409 of that  
11 Act (21 U.S.C. 348); or

12 (II) a new animal drug (or conversion  
13 product thereof) that is unsafe within the  
14 meaning of section 512 of that Act (21  
15 U.S.C. 360b);

16 (C) that consists in whole or in part of any  
17 filthy, putrid, or decomposed substance, or if  
18 the food is otherwise unfit for food;

19 (D) that has been prepared, packed, or  
20 held under insanitary conditions whereby it may  
21 have become contaminated with filth or ren-  
22 dered injurious to health;

23 (E) that, in whole or in part, is the prod-  
24 uct of a diseased animal or of an animal which  
25 has died otherwise than by slaughter;

(F) the container of which is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(G) that has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of that Act (21 U.S.C. 348);

(H)(i) of which any valuable constituent has been in whole or in part omitted or abstracted therefrom;

(ii) for which any substance has been substituted in whole or in part;

(iii) for which damage or inferiority has been concealed in any manner; or

(iv) to which any substance has been added or mixed or packed so as to increase the bulk or weight of the food, reduce the quality or strength of the food, or make the food appear better or of greater value than the food is;

(I) that bears or contains a color additive which is unsafe within the meaning of section 721(a) of that Act (21 U.S.C. 379e(a)); or

(J) that is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations promulgated under section 416 of that Act (21 U.S.C. 350e).

16 (A) the label of which—

17 (i) does not bear—

18 (I) the name of the food, in ac-  
19 cordance with subsection (c);

(II) in the case of the food being  
fabricated from 2 or more ingredients,  
the common or usual name of each in-  
gredient, except that spices,  
flavorings, and colorings may, when  
authorized by the appropriate agency

1                   head, be designated as spices,  
2                   flavorings, and colorings without nam-  
3                   ing each, provided that to the extent  
4                   that compliance is impracticable, or  
5                   results in deception or unfair competi-  
6                   tion, exemptions shall be established  
7                   by regulations promulgated by the  
8                   Secretary; or

9                   (III) an official inspection legend  
10                  directly on the food or on the con-  
11                  tainer of the food and such other in-  
12                  formation as the Secretary requires to  
13                  assure that the food will not have  
14                  false or misleading labeling and that  
15                  the public will be informed of the  
16                  manner of handling required to main-  
17                  tain the food in a wholesome condi-  
18                  tion;

19                  (B) the label of which is false or mis-  
20                  leading;

21                  (C) that is in a package or other container  
22                  the label of which does not bear—

23                  (i) the name and place of business of  
24                  the manufacturer, packer, or distributor;  
25                  or

(ii) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, subject to—

(I) reasonable variations permitted by the Secretary; and

(II) in the case of a small package or container, exemptions established by the Secretary by regulation;

10 (D) for which any word, statement, or  
11 other information required by the Secretary to  
12 appear on the label is not prominently placed  
13 on the label with such conspicuously (com-  
14 pared to any other words, statements, designs,  
15 or devices on the label) and in such terms as  
16 to render it likely to be read and understood by  
17 the ordinary individual under customary condi-  
18 tions of purchase and use;

19 (E) that is offered for sale under the name  
20 of another food;

21 (F) that is an imitation of another food,  
22 unless the label bears the word "imitation", in  
23 type of uniform size and prominence, and the  
24 name of the food imitated immediately after the  
25 word "imitation";

(G) the container of which is made,  
formed, or filled as to be misleading;

(H) that purports to be or is represented for special dietary uses but the label of which does not bear such information concerning the vitamin, mineral, and other dietary properties of the food as the Secretary, after consultation with the Secretary of Health and Human Services, determines to be, and by regulations prescribes as, necessary in order to inform purchasers fully of the value of the food for those uses; or

(5) POULTRY.—The term “poultry” has the meaning given the term in section 424(e) of the Federal Food, Drug, and Cosmetic Act.

1                         (6) SECRETARY.—The term “Secretary” means  
2                         the Secretary of Agriculture.

3                         (b) INSPECTIONS.—

4                         (1) IN GENERAL.—The Secretary shall inspect  
5                         establishments that process, package, and label food  
6                         intended for humans that is produced using animal  
7                         cell culture technology, derived from cell lines of live-  
8                         stock or poultry—

9                         (A) to ensure that—

10                         (i) the food is—

11                         (I) not adulterated; and

12                         (II) not misbranded; and

13                         (ii) the establishment is operating in  
14                         accordance with the regulations promul-  
15                         gated under paragraph (3).

16                         (2) OFFICIAL INSPECTION LEGEND.—The Sec-  
17                         retary shall establish an official inspection legend for  
18                         the food described in paragraph (1), which shall be  
19                         a symbol that shows that a product made from that  
20                         food was inspected and passed in accordance with  
21                         the regulations described in paragraph (3).

22                         (3) REGULATIONS.—The Secretary shall pro-  
23                         mulgate regulations regarding—

24                         (A) the manner and frequency of inspec-  
25                         tions required for—

**21**                   (c) LABELING.—

22 (1) IN GENERAL.—The Secretary shall—

(A) approve, before introduction into commerce, the labeling of food intended for humans that is produced using animal cell culture tech-

1                   nology, derived from cell lines of livestock or  
2                   poultry; and

3                   (B) verify the accuracy of that labeling  
4                   through inspection.

5                   (2) REQUIREMENTS.—The Secretary shall es-  
6                   tablish, after providing notice and an opportunity for  
7                   comment, any appropriate requirements in addition  
8                   to the requirements under paragraph (1) to ensure  
9                   the safety and accurate labeling of the food de-  
10                  scribed in paragraph (1)(A).

11                  (3) REGULATIONS.—The Secretary shall pro-  
12                  mulgate regulations—

13                  (A) to establish appropriate nomenclature  
14                  for the labeling approved under paragraph  
15                  (1)(A); and

16                  (B) to carry out paragraph (1)(B).

17                  (d) ENFORCEMENT.—The Secretary shall, pursuant  
18                  to relevant enforcement authorities governing the regula-  
19                  tion of amenable species (as defined in section 1 of the  
20                  Federal Meat Inspection Act (21 U.S.C. 601)), conduct  
21                  such enforcement action as is necessary to ensure that  
22                  food intended for humans that is produced using animal  
23                  cell culture technology, derived from cell lines of livestock  
24                  or poultry, that is adulterated or misbranded does not  
25                  enter or is removed from commerce.

1       (e) COLLABORATION WITH HHS.—In carrying out  
2 this section, the Secretary shall—

3               (1) review information shared by the Secretary  
4 of Health and Human Services under section 424(c)  
5 of the Federal Food, Drug, and Cosmetic Act;

6               (2) share appropriate information relating to  
7 food intended for humans that is produced using  
8 animal cell culture technology, derived from cell lines  
9 of livestock or poultry, with the Secretary of Health  
10 and Human Services, as appropriate; and

11              (3)(A) notify the Secretary of Health and  
12 Human Services if objectionable conditions at an es-  
13 tablishment are identified under an inspection under  
14 subsection (b)(1);

15              (B) collaborate with the Secretary of Health  
16 and Human Services to address those conditions  
17 with respect to cell harvesting; and

18              (C) rely on the Secretary of Health and Human  
19 Services to address those conditions with respect to  
20 initial cell collection, development and maintenance  
21 of qualified cell banks, and proliferation and dif-  
22 ferentiation of cells.

